

## General

### Guideline Title

Screening for hepatitis B virus infection in nonpregnant adolescents and adults: U.S. Preventive Services Task Force recommendation statement.

### Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for hepatitis B virus infection in nonpregnant adolescents and adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2014 Jul 1;161(1):58-66. [29 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force (USPSTF). Screening for hepatitis B virus infection: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2004 Feb. 4 p. [3 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Recommendations

### Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the levels of certainty regarding net benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

#### Summary of Recommendation and Evidence

The USPSTF recommends screening for hepatitis B virus (HBV) infection in persons at high risk for infection. (B recommendation)

#### Clinical Considerations

##### Patient Population Under Consideration

This recommendation applies to asymptomatic, nonpregnant adolescents and adults at high risk for HBV infection (including those at high risk who were vaccinated before being screened for HBV infection).

##### Assessment of Risk

A major risk factor for HBV infection is country of origin. The risk for HBV infection varies substantially by country of origin in foreign-born persons in the United States. Persons born in countries with a prevalence of HBV infection of 2% or greater account for 47% to 95% of those with chronic HBV infection in the United States (see Table 1 in the original guideline document). Another important risk factor for HBV infection is

lack of vaccination in infancy in U.S.-born persons with parents from a country or region with high prevalence ( $\geq 8\%$ ), such as sub-Saharan Africa, central and Southeast Asia, and China (see Figure 2 in the original guideline document). Because the prevalence of HBV infection may gradually change over time, it is important to note that some countries and regions with prevalence rates between 5% and 7% are considered to be highly endemic areas.

The Centers for Disease Control and Prevention (CDC) uses a prevalence threshold of 2% or greater to define countries with high risk for HBV infection. Because this threshold is substantially higher than the estimated prevalence of HBV infection in the general U.S. population (0.3% to 0.5%), it is a reasonable threshold for deciding to screen a patient population or risk group. Additional risk groups for HBV infection with a prevalence of 2% or greater that should be screened include human immunodeficiency virus (HIV)-positive persons, injection drug users, household contacts or sexual partners of persons with HBV infection, and men who have sex with men (see Table 2 in the original guideline document).

The CDC also recommends screening in persons receiving hemodialysis or cytotoxic or immunosuppressive therapy (for example, chemotherapy for malignant diseases, immunosuppression related to organ transplantation, and for rheumatologic and gastroenterologic disorders).

Some persons with combinations of risk factors who are not members of one of these risk factor groups may also be at increased risk for HBV infection. However, reliable information about combinations of risk factors is not available. Clinicians should exercise their judgment in deciding whether these persons are at sufficiently high risk to warrant screening. For example, screening is probably appropriate in settings that treat a large proportion of persons at increased risk, such as clinics for sexually transmitted infections; HIV testing and treatment centers; health care settings that provide services for injection drug users or men who have sex with men; correctional facilities; and institutions that serve populations from countries with a high prevalence of infection, including community health centers.

The prevalence of HBV infection is low in the general U.S. population, and most infected persons do not develop complications. Therefore, screening is not recommended in those who are not at increased risk. The USPSTF notes that high rates of HBV infection have been found in cities and other areas with high numbers of immigrants or migrant persons from Asia or the Pacific Islands or their adult children. Providers should consider the population they serve when making screening decisions.

### Screening Tests

The CDC recommends screening for hepatitis B surface antigen (HBsAg) with tests approved by the U.S. Food and Drug Administration, followed by a licensed, neutralizing confirmatory test for initially reactive results. Immunoassays for detecting HBsAg have a reported sensitivity and specificity greater than 98%. A positive HBsAg result indicates acute or chronic infection.

Testing for antibodies to HBsAg (anti-HBs) and hepatitis B core antigen (anti-HBc) is also done as part of a screening panel to help distinguish between infection and immunity. Acute HBV infection (within 6 months after infection) is characterized by the appearance of HBsAg and followed by the appearance of immunoglobulin M (IgM) anti-HBc. The disappearance of HBsAg and the presence of anti-HBs and anti-HBc indicate the resolution of HBV infection and natural immunity. Anti-HBc, which persist for life, are present only after HBV infection and do not develop in persons whose immunity to HBV is due to vaccination.

Persons who have received HBV vaccination have only anti-HBs. Diagnosis of chronic HBV infection is characterized by persistence of HBsAg for at least 6 months. Levels of HBV deoxyribonucleic acid (DNA) can fluctuate and are not a reliable marker of chronic infection.

### Treatment

#### *Antiviral Regimens*

The goals of antiviral treatment are to achieve sustained suppression of HBV replication and remission of liver disease to prevent cirrhosis, hepatic failure, and hepatocellular carcinoma. Interferons or nucleoside or nucleotide analogues are used to treat HBV infection. The U.S. Food and Drug Administration (FDA) has approved 7 antiviral drugs for treatment of chronic HBV infection: interferon- $\alpha 2b$ , pegylated interferon- $\alpha 2a$ , lamivudine, adefovir, entecavir, telbivudine, and tenofovir. Approved first-line treatments are pegylated interferon- $\alpha 2a$ , entecavir, and tenofovir. Combination therapies have been evaluated but are not approved by the U.S. FDA and are generally not used as first-line treatment because tolerability, efficacy, and rates of resistance are low.

Several factors affect the choice of antiviral drug, including patient characteristics, HBV DNA and serum aminotransferase levels, and hepatitis B e antigen (HBeAg) status. Biopsy is sometimes done to determine the extent of liver inflammation and fibrosis. Surrogate end points of antiviral treatment include loss of HBeAg and HBsAg, HBeAg seroconversion in HBeAg-positive patients, and suppression of HBV DNA to undetectable levels by polymerase chain reaction in patients who are HBeAg-negative and anti-HBe-positive. Duration of treatment varies depending on the time required to suppress HBV DNA levels and normalize alanine aminotransferase (ALT) levels, HBeAg status, the presence of cirrhosis, and the choice of drug.

## Vaccination

The current U.S. strategy to eliminate HBV transmission includes universal vaccination of all infants at birth and vaccination of adolescents and high-risk adults, such as injection drug users and household contacts of patients with HBV infection. Three doses of HBV vaccine result in a protective antibody response greater than 90% in adults and greater than 95% in adolescents. The CDC recommends that susceptible persons who are screened for HBV infection may, if indicated, receive the first dose of the HBV vaccine at the same medical visit.

### Screening Interval

Periodic screening may be useful in patients with ongoing risk for HBV transmission (for example, active injection drug users, men who have sex with men, and patients receiving hemodialysis) who do not receive vaccination. Clinical judgment should determine screening frequency, because the USPSTF found inadequate evidence to determine specific screening intervals.

### Definitions:

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be measured.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

### USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"><li>• The number, size, or quality of individual studies</li><li>• Inconsistency of findings across individual studies</li><li>• Limited generalizability of findings to routine primary care practice</li><li>• Lack of coherence in the chain of evidence</li></ul> <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>

Level of Certainty	Description
	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> <li>• The limited number or size of studies</li> <li>• Important flaws in study design or methods</li> <li>• Inconsistency of findings across individual studies</li> <li>• Gaps in the chain of evidence</li> <li>• Findings not generalizable to routine primary care practice</li> <li>• A lack of information on important health outcomes</li> </ul> <p>More information may allow an estimation of effects on health outcomes.</p>

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Hepatitis B virus infection

### Guideline Category

Prevention

Screening

### Clinical Specialty

Family Practice

Infectious Diseases

Internal Medicine

Preventive Medicine

### Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

### Guideline Objective(s)

- To provide the current U.S. Preventive Services Task Force (USPSTF) recommendations for the screening for hepatitis B virus (HBV)

infection and the supporting scientific evidence

- To update the 2004 USPSTF recommendation statement on screening for HBV infection

## Target Population

Asymptomatic, nonpregnant adolescents and adults at high risk for hepatitis B virus (HBV) infection (including those at high risk who were vaccinated before being screened for HBV infection)

## Interventions and Practices Considered

Screening for hepatitis B virus (HBV)

## Major Outcomes Considered

- Key Question 1: What are the benefits of screening for hepatitis B virus (HBV) versus no screening in asymptomatic, nonpregnant adolescents and adults on morbidity, mortality, and disease transmission?
- Key Question 2: What are the harms of screening for HBV infection (e.g., labeling, anxiety, and harms of confirmatory tests, including biopsy)?
- Key Question 3: How well do different screening strategies identify individuals with HBV infection (e.g., strategies that target persons from high-prevalence countries, men who have sex with men, injection drug users, immunization history, or other risk factors)?
- Key Question 4: In nonpregnant adolescents and adults with no evidence of HBV immunity on screening, how effective is HBV vaccination for improving clinical outcomes?
- Key Question 5: In nonpregnant adolescents and adults with chronic HBV infection, how effective is antiviral treatment at improving intermediate outcomes (virological or histological improvement or clearance of hepatitis B e antigen [HBeAg])?
- Key Question 6: In nonpregnant adolescents and adults with chronic HBV infection, how effective is antiviral treatment at improving health outcomes?
- Key Question 7: In nonpregnant adolescents and adults with chronic HBV infection, how effective is education or behavior change counseling in reducing transmission and improving health outcomes?
- Key Question 8: What are the harms associated with antiviral treatment for HBV infection?
- Key Question 9: Do improvements in intermediate outcomes improve final health outcomes?

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Pacific Northwest Evidence-Based Practice Center (EPC), Oregon Health & Science University for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Sources and Searches

A research librarian searched MEDLINE (1946 through January 2014), the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and PsycINFO. EPC staff supplemented electronic searches by reviewing reference lists of retrieved articles.

## Study Selection

At least 2 reviewers independently evaluated each study to determine inclusion eligibility. For screening, EPC staff included randomized trials and observational studies that compared different screening strategies in asymptomatic adults without known abnormal liver enzyme levels. They also reported clinical outcomes or the sensitivity and number needed to screen (NNS) to identify 1 hepatitis B virus (HBV)-infected person or provided the data to calculate these variables.

For treatment, EPC staff included placebo-controlled trials of vaccination of adolescents and adults without known immunity to HBV and relevant systematic reviews. For antiviral therapy, EPC staff included trials of monotherapy with a medication approved by the U.S. Food and Drug Administration versus placebo or no treatment or first-line antiviral therapies (entecavir, tenofovir, or pegylated interferon- $\alpha$ 2a) versus other approved therapies (adefovir, nonpegylated interferon, lamivudine, or telbivudine) that reported clinical outcomes (mortality, cirrhosis, hepatic decompensation, hepatocellular carcinoma, need for transplantation, or disease transmission), intermediate outcomes (histologic, virologic, or serologic), or harms (withdrawals due to adverse events, serious adverse events, or overall adverse events). EPC staff included trials of interferon- $\alpha$ 2a (not approved for HBV infection) that reported clinical outcomes because evidence for interferon- $\alpha$ 2b and pegylated interferon was limited. For the association between achieving an intermediate outcome after antiviral treatment and subsequent clinical outcomes, EPC staff included cohort studies that reported adjusted risk estimates.

EPC staff included only English-language articles and excluded studies published only as abstracts. EPC staff excluded trials of persons who did not respond to prior antiviral therapy or those who had virologic relapse and did not evaluate drug resistance as an outcome. They excluded studies of patients co-infected with HIV or hepatitis C virus, transplant recipients, and patients receiving hemodialysis. EPC staff excluded systematic reviews of antiviral therapies unless the staff were unable to abstract the primary studies because they were in a foreign language. Appendix Figure 2 in the Evidence Review shows the summary of evidence search and selection (see the "Availability of Companion Documents" field).

## Number of Source Documents

- Key Question 1: 0 studies
- Key Question 2: 0 studies
- Key Question 3: 1 study
- Key Question 4: No studies on long-term clinical outcomes
- Key Question 5: 30 studies (in 31 publications)
- Key Question 6: 16 studies (in 18 publications)
- Key Question 7: 0 studies
- Key Question 8: 29 studies (in 28 publications)
- Key Question 9: 10 studies

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Two investigators independently applied criteria developed by the U.S. Preventive Services Task Force (USPSTF) to rate the quality of each study as good, fair, or poor (see Appendix A5 in the Evidence Synthesis [see the "Availability of Companion Documents" field]).

## Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

# Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Pacific Northwest Evidence-Based Practice Center (EPC), Oregon Health & Science University for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

## Data Abstraction and Quality Rating

One investigator abstracted details about the study design, patient population, setting, screening method, interventions, analysis, follow-up, and results. A second investigator reviewed data for accuracy. Two investigators independently applied criteria developed by the USPSTF to rate the quality of each study as good, fair, or poor. Discrepancies were resolved through consensus.

## Data Synthesis and Analysis

EPC staff assessed the aggregate internal validity (quality) of the body of evidence for each key question (good, fair, or poor) on the basis of the number, quality, and size of studies; consistency of results; and directness of evidence.

For antiviral therapy and vaccination, EPC staff conducted meta-analyses to calculate relative risks using the DerSimonian–Laird random-effects model (Review Manager, version 5.2, Nordic Cochrane Centre, Cochrane Collaboration, Copenhagen, Denmark). Primary analyses for antiviral therapy were based on total follow-up (including events after discontinuation of treatment), although EPC staff conducted sensitivity analyses of events during antiviral therapy. For harms, they analyzed events that occurred during antiviral therapy.

For all analyses, EPC staff stratified results by antiviral drug. Statistical heterogeneity was assessed by using the I<sup>2</sup> statistic. They did additional analyses in which trials were stratified by study quality, duration of follow-up (shorter or longer than 1 year), hepatitis B e antigen (HBeAg) status, and inclusion of patients with cirrhosis.

# Methods Used to Formulate the Recommendations

## Balance Sheets

## Expert Consensus

# Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid\*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

\*A, B, C, D, and I (*Insufficient*) represent the letter grades of recommendation or statement of insufficient evidence assigned by the USPSTF after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the USPSTF constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the USPSTF process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term certainty will now be used to describe the USPSTF's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of the Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see the "Availability of Companion Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med*. 2007;147(12):871-875. [5 references].

## Rating Scheme for the Strength of the Recommendations

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A	The USPSTF recommends the service. There is high certainty	Offer/provide this service.



Grade	Grade Definitions	Suggestions for Practice
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be measured.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

### USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> <li>• The number, size, or quality of individual studies</li> <li>• Inconsistency of findings across individual studies</li> <li>• Limited generalizability of findings to routine primary care practice</li> <li>• Lack of coherence in the chain of evidence</li> </ul> <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> <li>• The limited number or size of studies</li> <li>• Important flaws in study design or methods</li> <li>• Inconsistency of findings across individual studies</li> <li>• Gaps in the chain of evidence</li> <li>• Findings not generalizable to routine primary care practice</li> <li>• A lack of information on important health outcomes</li> </ul> <p>More information may allow an estimation of effects on health outcomes.</p>

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

Comparison with Guidelines from Other Groups

## Description of Method of Guideline Validation

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the USPSTF Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comment. A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 11 February to 10 March 2014. Some comments requested clarification about risk factors, screening tests, vaccinations, and screening frequency. Others asked for a definition of "immunosuppressed."

In response to these comments, the USPSTF added language about populations that are at risk in the Clinical Considerations section. The USPSTF also added language to clarify about screening tests and vaccination. Language was added to the section on research gaps. Text was added to address screening frequency and to clarify the definition of "immunosuppressed."

Comparison with Guidelines from Other Groups. Recommendations for screening from the following groups were discussed: the Centers for Disease Control and Prevention (CDC), the American Association for the Study of Liver Diseases, the Institute of Medicine, and the American Academy of Family Physicians.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

#### Benefits of Detection and Early Intervention

The U.S. Preventive Services Task Force (USPSTF) found no randomized, controlled trials that provide direct evidence of the health benefits (that is, reduction in morbidity, mortality, and disease transmission) of screening for hepatitis B virus (HBV) infection in asymptomatic, nonpregnant adolescents and adults.

The USPSTF found adequate evidence that HBV vaccination is effective at decreasing disease acquisition.

The USPSTF found convincing evidence that antiviral treatment in patients with chronic HBV infection is effective at improving intermediate outcomes (that is, virologic or histologic improvement or clearance of hepatitis B e antigen [HBeAg]) and adequate evidence that antiviral regimens improve health outcomes (such as reduced risk for hepatocellular carcinoma). The evidence showed an association between improvement in intermediate outcomes after antiviral therapy and improvement in clinical outcomes, but outcomes were heterogeneous and the studies had methodological limitations.

The USPSTF found inadequate evidence that education or behavior change counseling reduces disease transmission.

The prevalence of HBV infection differs among various populations. As a result, the magnitude of benefit of screening varies according to risk group.

The USPSTF concludes that screening is of moderate benefit for populations at high risk for HBV infection, given the accuracy of the screening test and the effectiveness of antiviral treatment.

## Potential Harms

### Harms of Detection and Early Intervention

The U.S. Preventive Services Task Force (USPSTF) found inadequate evidence on the harms of screening for hepatitis B virus (HBV) infection. Although evidence to determine the magnitude of harms of screening is limited, the USPSTF considers these harms to be small to none.

The USPSTF found adequate evidence that antiviral therapy regimens are associated with a higher risk for withdrawal due to adverse events than placebo. However, trials found no difference in the risk for serious adverse events or the number of participants who had any adverse event. In addition, most antiviral adverse events were self-limited with discontinuation of therapy. The USPSTF found adequate evidence that the magnitude of harms of treatment is small to none.

## Qualifying Statements

### Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

## Implementation of the Guideline

### Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its [Web site](#) . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size

Guide to Clinical Preventive Services.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

## Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Staying Healthy

### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for hepatitis B virus infection in nonpregnant adolescents and adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2014 Jul 1;161(1):58-66. [29 references] [PubMed](#)

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

## Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

## Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services or its agencies.

## Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality support the operations of the USPSTF.

## Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

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*\*Members of the USPSTF at the time this recommendation was finalized. For a list of current Task Force members, go to <http://www.uspreventiveservicestaskforce.org/Page/Name/our-members> .*

## Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. USPSTF members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

*Disclosures*: Dr. Owen reports support from the Agency for Healthcare Research and Quality during the conduct of the study. Authors not named here have disclosed no conflicts of interest. Authors followed the policy regarding conflicts of interest described at [www.uspreventiveservicestaskforce.org/methods.htm](http://www.uspreventiveservicestaskforce.org/methods.htm) . Disclosures can also be viewed at [www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M14-1018](http://www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M14-1018) .

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force (USPSTF). Screening for hepatitis B virus infection: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2004 Feb. 4 p. [3 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

## Availability of Companion Documents

The following are available:

Evidence Reviews:

- Chou R, Dana T, Bougatsos C, Blazina I, Khangura J, Zakher B. Screening for hepatitis B virus infection in adolescents and adults: A systematic review to update the U.S. Preventive Services Task Force recommendation. *Ann Intern Med*. 2014;161:31-45.
- Chou R, Dana T, Bougatsos C, Blazina I, Zakher B, Khangura J. Screening for hepatitis B virus infection in nonpregnant adolescents and adults: Systematic review to update the 2004 U.S. Preventive Services Task Force recommendation. Evidence synthesis No. 110. AHRQ Publication No. 12-05172-EF-1. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2014 May. 180 p.

Electronic copies: Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#) .

Background Articles:

- Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. *Ann Intern Med* 2007;147:123-127.
- Guirgis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. *Ann Intern Med* 2007;147:117-122.
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med* 2007;147:871-875.

Electronic copies: Available from [USPSTF Web site](#) .

The following are also available:

- Screening for hepatitis B virus infection in nonpregnant adolescents and adults. Clinical summary of U.S. Preventive Services Task Force recommendation. 2014. 1 p. Electronic copies: Available from the [USPSTF Web site](#) .
- The guide to clinical preventive services, 2014. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2014. 144 p. Electronic copies: Available from the [AHRQ Web site](#) . See the related QualityTool summary on the [Health Care Innovations Exchange Web site](#) .
- A continuing medical education (CME) activity is available from the [Annals of Internal Medicine Web site](#) .

The [Electronic Preventive Services Selector \(ePSS\)](#)  is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on the current, evidence-based recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

## Patient Resources

The following are available:

- Screening for hepatitis B virus infection in nonpregnant adolescents and adults. Understanding Task Force recommendations. Rockville (MD): U.S. Preventive Services Task Force. Consumer fact sheet. 2014 May. 4 p. Electronic copies: Available from the [U.S. Preventive](#)



Services Task Force (USPSTF) Web site .

- Screening for hepatitis B virus infection: U.S. Preventive Services Task Force recommendation statement. Summaries for patients. Ann Intern Med. 2014;161(1):I-28. Available from the [Annals of Internal Medicine Web site](#) .
- Women: stay healthy at any age. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. Agency for Healthcare Research and Quality (AHRQ) Pub. No. 14-IP007-A. 2014 Mar. 5 p. Electronic copies: Available in [English](#)  and [Spanish](#)  from the AHRQ Web site. See the related QualityTool summary on the [Health Care Innovations Exchange Web site](#) .
- Men: stay healthy at any age. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP006-A. 2014 Mar. 5 p. Electronic copies: Available in [English](#)  and [Spanish](#)  from the AHRQ Web site. See the related QualityTool summary on the [Health Care Innovations Exchange Web site](#) .
- Women: stay healthy at 50+. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP002-A. 2014 Mar. 5 p. Electronic copies: Available in [English](#)  and [Spanish](#)  from the AHRQ Web site.
- Men: stay healthy at 50+. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP009-A. 2014 Mar. 5 p. Electronic copies: Available in [English](#)  and [Spanish](#)  from the AHRQ Web site.

Print copies: Available in English and Spanish from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to <http://www.ahrq.gov/research/publications/index.html>  or call 1-800-358-9295  (U.S. only).

Myhealthfinder is a tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at [www.healthfinder.gov](http://www.healthfinder.gov)

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Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

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